6 Dunder REP	aperwork Reduction Act of 1995.	no person	s are required to respond to a collection	nt and Trai	pproved for use through 04/30/2003. OMB 0651-d demark Office; U.S. DEPARTMENT OF COMMEI mation unless it displays a valid OMB control num
			Application Number	10/6	96,044
<b>, *//</b> T	TRANSMITTAL FORM  (to be used for all correspondence after initial filing)		Filing Date	Octob	per 29, 2003
No. of London			First Named Inventor	Robe	rt M. Noack
(to be used fo			Art Unit		
			Examiner Name		
Total Number	of Pages in This Submission		Attorney Docket Number	009	03
		ENC	LOSURES (Check all tha	t apply)	
Amendar  Extension  Express  Informat  Certified Docume  Responsion	se to Missing Parts/ ete Application Response to Missing Parts		Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a  Provisional Application  Power of Attorney, Revocation  Change of Correspondence Addr  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)		After Allowance Communication to a Technology Center (TC)  Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter  Other Enclosure(s) (please Identify below):  Return Postcard
ا ا	under 37 CFR 1.52 or 1.53				
	SIGNA	TURE C	OF APPLICANT, ATTORN	EY, OF	RAGENT
Firm or Individual	Karen B. King Reg. No. 41,898				
Signature	Karen 1	ma			
Date	March 9, 2004	0			

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Connie L. Park

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Robert M. Noack et al )	DOCKET NO.:	00903
SERIAL NO.:	10/696,044	GROUP ART UNIT:	
FILED:	October 29, 2003 )	EXAMINER:	
TITLE:	ORAL EXTENDED RELEASE MAKING AND USING THE SA		ODS OF
DATE:	March 9, 2004		

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Connie L. Park

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants hereby submit copies of patents, publications or other information of which they are aware that they believe may be material to the examination of this application, and in respect of which there may be a duty to disclose under 37 CFR § 1.56. A list of all enclosed documents is provided in a PTO Form 1441, transmitted herewith.

This information disclosure statement is being filed within three months of the filing date of the above-cited patent application or prior to the mailing of a first Office action on the merits, in accordance with 37 CFR § 1.97(b). Accordingly, Applicants

respectfully request that the statement be considered by the Office, in the course of prosecution of the application.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR §1.97(g)), an admission that the information cited is or is considered to be, material to patentability, or that no other material information exists.

Dated: 3/9/04

Karen B. King

Reg. No.: 41,898

PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known					
Application Number	10/696,044	•			
Filing Date	October 29, 2003				
First Named Inventor	Robert M. Noack et al.				
Art Unit	Not Yet Known				
Examiner Name	Not Yet Known				
Attorney Docket Number	00903/1/US				

			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 3,885,026	05/20/75	H. Heinemann et al.	
		US- 4,096,238	06/20/78	A. Zaffaroni et al.	
		US- 4,134,943	01/16/79	K. Knitsch et al.	
		US- 4,244,941	01/13/81	C. Lerk	
		<sup>US-</sup> 4,687,660	08/18/87	R. Baker et al.	
		<sup>US-</sup> 4,837,030	06/06/89	J. Valorose et al.	
		<sup>US-</sup> 4,871,549	10/03/89	Y. Ueda et al.	
		US- 4,880,631	11/14/89	J. Haslam et al.	
		US- 4,892,742	01/09/90	N. Shah	
		US- 4,919,938	04/24/90	C. Lovegrove et al.	
		US- 4,946,686	08/07/90	G. McClelland et al.	
		US- 4,994,273	02/19/91	G. Zentner et al.	
		US- 5,055,306	10/08/91	B. Barry et al.	
		US- 5,102,665	04/07/92	A. Schaeffer	
		US- 5,175,003	12/29/92	R. Goldman	
		US- 5,260,069	11/09/93	C. Chen	
		US- 5,356,467	10/18/94	B. Oshlack	
		US- 5,458,887	10/17/95	C. Chen et al.	
		US- 5,505,966	04/09/96	P. Edman et al.	

	FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T <sup>€</sup>
	WO 90/01926	03/08/90	Himedics, Inc.		
	WO 93/00889	01/21/93	L.C. Phar-Chem LTD.		
	 WO 94/22431	10/13/94	Kabi Pharmacia AB		
	WO 97/25979	07/24/97	Perio Products LTD		
	WO 98/03161	01/29/98	Dexcel LTD		
	WO 98/15265	04/16/98	Danbiosyst UK Limited		

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Signature	Considered	
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Substitute for form 1449/PTO		Col	Complete if Known		
	,	Application Number	10/696,044		
INFORM	ATION DISCLOSURE	Filing Date	October 29, 2003		
		First Named Inventor	Robert M. Noack et al.		
	ENT BY APPLICANT	Art Unit	Not Yet Known		
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Sheet 2	of 4	Attorney Docket Number	00903/1/US		

Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,520,931	05/28/96	C. Persson et al.	
		US- 5,607,685	03/04/97	M. Cimbollek et al.	
		US- 5,609,884	03/11/97	S. Desai	
		US- 5,656,294	08/12/97	D. Friend et al	
		<sup>US-</sup> 5,656,296	08/12/97	S. Khan et al.	
		US- 5,670,170	09/23/97	F. Grimmett et al.	
		US- 5,711,967	01/27/98	R. Juch	
		US- 5,840,332	11/24/98	E. Lerner et al.	
		US- 5,881,388	03/16/99	K. Pratt et al	
		US- 5,900,252	05/04/99	M. Calanchi et al.	
		US- 6,004,581	12/21/99	S. Jepsen et al.	
		<sup>US-</sup> 6,068,856	05/30/00	G. Sachs et al.	
		<sup>US-</sup> 6,068,859	05/30/00	W. Curatolo et al.	
		US- 6,074,669	06/13/00	V. Nagaprasad et al.	
		US- 6,150,410	11/21/00	K. Engh et al.	
		US- 6,228,398	05/08/01	J. Devane et al.	
		US- 6,231,888	05/15/01	E. Lerner et al.	
		US- 6,287,599	08/11/01	B. Burnside et al.	
		US- 6,312,728	11/06/01	E. Beiman et al.	

-,		FORE	IGN PATENT DOC	JMENTS	-	
Examiner Cite No.1		Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Or Relevant Figures Appear	T <sup>6</sup>	
		WO 98/22095	05/28/98	Procter & Gamble Co.		
		WO 98/26767	06/25/98	Poli Industria Chimica S.P.A.		
		WO 99/00136	01/07/99	J. Rowe		
		WO 99/66904	12/29/99	Theratech Inc.		
		WO 00/25757	05/11/00	Merck & Co., Inc.		
		WO 00/69420	11/23/00	Coraltis Ltd.		

Examiner	Date	
Signature	Considered	

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Complete if Known Substitute for form 1449/PTO Application Number 10/696,044 Filing Date October 29, 2003 INFORMATION DISCLOSURE First Named Inventor Robert M. Noack et al. STATEMENT BY APPLICANT Art Unit Not Yet Known (Use as many sheets as necessary) **Examiner Name** Not Yet Known Sheet 3 Attorney Docket Number 00903/1/US

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	
	 Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			Т
	WO 01/05430 A1	01/25/01	Merck & Co., Inc.		
	WO 01/45706	06/28/01	Pharmacia Corporation		
	EP 0 310 814	10/06/87	American Cyanamid Co.		
	EP 0 365 947 B1	05/02/90	DIB Limited		
	EP 0 572 942	12/08/93	Monsanto Italiana S.p.A.	,	

Examiner		Date	
Signature	İ	Considered	

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	Application Number	10/696,044	
NFORMATION DISCLOSURE	Filing Date	October 29, 2003	
STATEMENT BY APPLICANT	First Named Inventor	Robert M. Noack et al.	
(Use as many sheets as necessary)	Art Unit	Not Yet Known	
(000 us many shoots as nocessary)	Examiner Name		

Attorney Docket Number

Sheet

4

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LEE F. SIEW, ABDUL W. BASIT, AND J. MICHAEL NEWTON, "The Potential of Organic-Based Amylose-Ethylcellulose Film Coatings as Oral Colon-Specific Drug Delivery Systems", AAAPS PharmSciTech, 2000, 9 pages,1 (3), article 22, The School of Pharmacy, London, UK	
		SURELEASE, Product Information, Product Specification, Formula No. E-7-19010, (2001), Colorcon, 2 pages	
		SURELEASE, Technical Data; Coating Application, (2001), Colorcon, 2 pages	
		SURETERIC, Product information; Product Data Sheet; Formula: YAE-6-18107, (2000), Colorcon, 2 pages	
		BILL ST. JOHN, "Controlled Delivery Oral Dosage Forms in the New Millennium", Pharmaceutical Manufacturing and Packing Sourcer, © 2000, 4 pages, Ballantyne Ross Ltd International Media, London, UK	
		ZEIN, 3 pages, downloaded from internet at www.freeman@lanline.com on 9/6/2002, Freeman Industries LLC, (last modified 6/13/2002)	
		ACRYL-EZE, Technical Data Sheet; Enteric Coating Stability, (2001), Colorcon, 2 pages	
		SURETERIC, Information sheet, Preparation & Use Guidelines; © 2001 Colorcon, 2 pages	
		FUKUI ET AL., "Preparation of enteric coated timed-release press-coated tablets and evaluation of their function by in vitro and in vivo test for colon targeting", Int. J. of Pharm., 19 May 2000, pages 7-15, vol. 204	

Examiner	Date	
Signature	 Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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